

501(k) SUMMARY

DEC 17 2003

SUBMITTERS IDENTIFICATION

Applicant's Name and Street Address: IS2 Medical Systems Inc.
20 Gurdwara Rd., Units 3-10
Ottawa, Ontario, Canada
K2E 8B3

Contact Person: Victor Woodburn, Manager Quality and Regulatory

Telephone and Fax Number of Contact Person: T- (613) 228-8755, F - (613) 228-8228

Address of Manufacturing Site: Same as Applicant's Address noted above

Date of Submission: September 30, 2003

DEVICE NAME

Device Name (Common): Gamma Camera

Proprietary Name: Mobile Rectangular Single Head Camera (MSR))

Classification Name: Emission Computed Tomography System

Product Code: 90-KPS

CFR: 21CFR 892.1200

Device Class: II

Predicate Device: Rectangular Single Head Camera (SR)

510(k) No.: K982045
(Predicate)

INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the Mobile Rectangular Single Head Camera (MSR), manufactured by IS2 Medical Systems Inc., is substantially equivalent to the Rectangular Single Head Camera (SR) which has previously been through the 510(k) premarket notification process. The Mobile Rectangular Single Head Camera (MSR) nuclear imaging system has a single rectangular field of view detector heads.

501(k) SUMMARY

INTENDED USE

The intended use of the Mobile Rectangular Single Head Camera (MSR) is to detect the location and distribution of gamma ray emitting radionuclides in the body and store data for analysis. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts and accessories.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the Mobile Rectangular Single Head Camera (MSR) is the same range of studies to that of the Rectangular Single Head Camera (SR). The detector head is identical in hardware and software. The gantry of the Mobile Rectangular Single Head Camera (MSR) is optimized for being attached to a mobile platform which is transported from location to location in a truck and has the same range of automatic clinical motions of the Rectangular Single Head Camera (SR).

The Mobile Rectangular Single Head Camera (MSR) has been deemed safe and effective and is certified to the same electrical safety standards as the predicate device by a third party organization prior to use on patients. A matrix was constructed comparing the features and intended use of the Mobile Rectangular Single Head Camera (MSR) with the predicate device. We conclude that the Mobile Rectangular Single Head Camera (MSR) is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Mr. Victor Woodburn
Manager, Quality and Regulatory
IS2 Medical Systems, Inc.
20 Gurdwara Road, Units 3-10
Ottawa, Ontario, K2E 8B3
CANADA

Re: K032779
Trade/Device Name: Mobile Rectangular Single
Head Camera (MSR)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed
tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: September 5, 2003
Received: September 18, 2003

Dear Mr. Woodburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

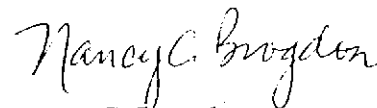
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (K032779)

Device Name *Mobile Rectangular Single Head Camera (MSR)*

Indications for Use: *The intended use of the Mobile Rectangular Single Head Camera is to detect the location and distribution of gamma ray emitting radionuclides in the body and store data for analysis. This device resides on a mobile platform and includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts and accessories.*

To detect or image the distribution of radionuclides in the body or organ using the following technique(s):

	YES	NO	Energy Range (keV)
(a) Planar Imaging	<input checked="" type="checkbox"/>	<input type="checkbox"/>	50 – 400 keV
(b) Whole Body Imaging	<input checked="" type="checkbox"/>	<input type="checkbox"/>	50 – 400 keV
(c) Tomographic Imaging (SPECT) for non Positron emitter	<input checked="" type="checkbox"/>	<input type="checkbox"/>	50 – 400 keV
(d) Positron imaging by coincidence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
(e) Positron imaging without coincidence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
(f) Other indication(s) in the device label, but not included in the above list	<input type="checkbox"/>	<input checked="" type="checkbox"/>	None

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K 032779

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐